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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,516	11/14/2001	David A. Shafer	D6431	8007

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/992,516

Applicant(s)

SHAFER, DAVID A.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 9-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/14/04 has been entered.

Status of Claims

Claims 7 and 9-22 are pending and under consideration.

Claims 1-6, 8 and 23-54 have cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

In view of the amendments to the claims the rejection no longer applies.

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Claim Rejections - 35 USC § 112. second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 9-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. It is not clear within the claimed context, a "pipette-based" dispenser i.e., in what respect the dispenser is based or like a pipette. Also, the term "small" is a relative term, which renders the claim indefinite. The term "small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear as to the size of said small droplets.

B. Claims 19-22 does not further limit the claimed method of forming a miniarray. These claims are drawn to a different method i.e., of using.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Amended claims 7 and 9-10 and 12-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Brown or Van Ness in view of either Chee et al (USP 6,429,027) or Tisonne et al (USP 6,063,339).

Brown et al discloses at col. 3, line 23 up to col.4, line 59 a method of forming a microarray of analyte-assay regions on a solid support, where each region in the array has a known amount of a selected, analyte-specific reagent. The method comprises loading a solution of a selected analyte-specific reagent in a reagent-dispensing device having an elongate capillary channel (pipette-based dispensers as claimed) (i) formed by spaced-apart, coextensive elongate members, (ii) adapted to hold a quantity of the reagent solution and (iii)

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having a tip region at which aqueous solution in the channel forms a meniscus. The tip of the dispensing device is tapped against a solid support at a defined position on the support surface with an impulse effective to break the meniscus in the capillary channel, and deposit a selected volume of solution on the surface. The two steps are repeated until the desired array is formed. See further col. 6, line 64 up to col. 9, line 50 and the claims.

Van Ness is discussed in the last Office action and below. Neither Brown nor Van Ness discloses a miniarray as claimed. However, Chee discloses at col. 6, lines 1-43 an array compositions can be made into a high density, moderate density, low or very low density array. Chee discloses that the size of the array will depend on the composition and end use of the array. Low density arrays are generally less than 10,000, with from about 1,000 to about 5,000 cm being preferred. Very low density arrays are less than 1,000, with from about 10 to about 1000 being preferred, and from about 100 to about 500cm being particularly preferred. In addition, one advantage of the present compositions is that particularly through the use of fiber optic technology.

Tisone discloses at col. 25, lines 19-22 that a dispenser can be programmed so as to transform one or more well plate

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arrays into a new or different high or low density array. For example, a series of two dimensional arrays may be transformed into rows or columns of a larger high-density array, or arrays may be transposed or inverted. Direct 1:1 mapping can also be achieved by operating the dispense heads in parallel synchronous line mode to produce 8 drops on each slide with a spacing of 9 mm. Other modes and variations for the use and operation of the invention will be apparent to those skilled in the art.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make a miniarray (i.e., low density array) using the method of Brown as taught by either Chee or Tisone. Each of Chee or Tisone positively teaches that either a high density (microarray) or a low density miniarray can be made. That such arrays are useful in fiber optic technology would motivate one in skill in the art to use either a high or low density array as taught by e.g., Chee.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brown in view of either Chee or Tisone as applied to claims 7 and 9-10 and 12-22 above, and further in view of (Lange, abstract).

Brown is discussed, above. Brown does not disclose a disposable tips dispensers. However, Lange discloses the use of

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a disposable pipette (see the abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a disposable unit in the method of Brown as taught by Lange. A disposable dispenser unit would obviously produce a contamination free device for pipetting liquids. One would have been motivated to use a disposable unit since contaminants can produce false background during hybridization.

Response to Arguments

Applicant argues that the present invention teaches a CTC spacing of 1-3 mm, which is at least more than double of 400mm taught in Brown et al.

In reply, Brown does not teach 400mm but 400 um (i.e., 0.4 mm) which approximates the claimed about 1 mm. Hence, this is not more than double the present about 1 mm.

Applicant disagrees that the CTC spots or locations dispensing is a result effective variable well within the realm of one having ordinary skill in the art. Applicant argues that the suggestion or teaching to make the claimed invention must be found in the prior art, not in applicant's disclosure.

In response, such CTC determination, as evident from the prior art teaching, are the typical ranges used in the prior art and in the present claim. This is not based on the instant

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disclosure teaching. Rather, from the teachings of e.g., Van Ness. [The disclosure specifically at paragraph bridging pages 41-42 recognize this as a result effective variable i.e., the value is typical in the art.]

Applicant argues that Brown and Lange do not teach or suggest modifying the microarray and increasing the CTC spacing to 1-3 mm(sic, about) to change the microarray into miniarray as claimed herein.

In response, it is not patentably significant to decrease the size of an array since the size of the article under consideration is not ordinarily a matter of invention. (See the newly cited Chee or Tisone, above).

Applicant argues that the passage at col. 6, lines 54-60 merely describes general features of the microarray, e.g., spot size and distance between the spots. It does not teach or suggest any relationship between spot size and distance between the spots, let alone teach or suggest modifying the distance between the spots due to the size of the spots.

In reply, Van Ness states "...a variety of printing methods are available for applying...to a solid substrate in an array pattern. As a general guideline, the delivery mechanism must be capable of position very small amounts of liquids ...in small regions... where the regions are very close to one another (e.g.,

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25-500um center to center distance)..." [It is of interest to note the paragraph bridging pages 41 and 42 of the instant disclosure as to the CTC distance of the spots as dependent e.g., on the well use. All of the method steps of Brown or Van Ness are similar to the instant claimed process steps. Applicants claim process is alleged to result in a miniarray as opposed to the prior art microarray. However, as well known in the art, it will be within the ordinary skill in the art to make the size of array one desires, as taught by e.g., Chee above.


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

August 6, 2004